NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JULIE CARR-DAVIS, as surviving Spouse and Administratrix of the ESTATE OF RALPH R. CARR, Deceased, Plaintiff, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	Civil Action No. 07-1098 (FLW) **OPINION**

WOLFSON, District Judge:

Plaintiff Julie Carr-Davis ("Plaintiff"), as surviving spouse and administratix of the Estate of Ralph R. Carr, ("Decedent" or "Mr. Carr") brings the instant suit on behalf of Decedent against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that Decedent suffered injuries as a result of Defendants' design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Amended Complaint ("Amended Complaint") asserts various Missouri state and common law claims against Defendants, including Failure-to-Warn, Defective

Design, Manufacturing Defect and Negligence.[1] Before the Court is Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under Missouri law. For the reasons that follow, Defendants' motion for summary judgment is GRANTED and all counts in the Amended Complaint are dismissed.[2]

BACKGROUND[3]

A. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food

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[1] In her Original Complaint, Plaintiff initially asserted New Jersey state and common law claims against Defendants. Following two separate decisions rendered by the New Jersey Supreme Court in 2007, Plaintiff voluntarily dismissed those New Jersey claims and amended her Complaint to assert causes of action arising only under Missouri state law. See Opinion dated December 30, 2009, pp. 2-3. Therefore, Missouri law controls on this motion.

[2] Pending before this Court are related cases filed by other plaintiffs who were allegedly injured by ingesting Plavix, albeit their injuries may be different than those suffered by Mr. Carr in this case. In those related cases, Defendants have also filed summary judgment motions. Moreover, the Court is aware that there are numerous cases concerning Plavix brought against Defendants in other state and federal courts across the country. Because each plaintiff's personal circumstances differ, the Court's findings in this Opinion only represent the application of pertinent state law, i.e., Missouri, to the facts presented in this particular case. That said, to avoid unnecessary duplication of effort in my several related cases and to conserve judicial resources, I cite to the analysis of similar legal issues in my published opinion in Solomon v. BMS, Civil Action No. 07-1102 (FLW) (Slip Op.), where appropriate.

[3] The following facts are undisputed unless otherwise noted.

and Drug Administration ("FDA") for use as monotherapy, i.e., taken without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral vascular disease ("PVD"). See Defs. Statement, ¶ 2. Thereafter, the FDA approved Plavix for dual therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").[4] Id. at ¶ 3.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, labeling on Plavix included certain information on that risk. The label provides:

> **PRECAUTIONS**
>
> **General**
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.
>
> *GI Bleeding*: PLAVIX prolongs the bleeding time. In

[4] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not receive enough blood because of plaque narrowing or blocking of the arteries leading to the heart. Commonly, ACS includes, inter alia, heart attacks and irregular chest pains known as unstable angina. See, e.g., Frederick G. Kushner, et al., 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infraction and Guidelines on Percutaneous Coronary Intervention, 54 J. Am. C. Cardiology 2205, 2212 (2009).

CAPRIE[5], PLAVIX was associated with a rate of gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.

* * *

Information for Patients

Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician.

* * *

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3)[6]. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at

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[5] According to BMS, the clinical evidence for the risks of PLAVIX is derived from two double-blind trials: (i) the CAPRIE study (Clopidogrel v. Aspirin in Patients at Risk of Ischemic Events), a comparison of PLAVIX to aspirin, and (ii) the CURE study (Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events), a comparison of PLAVIX to placebo, both given in combination with aspirin and other standard therapy. See February 2002 Plavix Labeling, p.3. While Plaintiff contests the accuracy of these clinical trials, her arguments are not relevant to my disposition of this case. They are addressed in detail, however, in my opinion in Solomon.

[6] Table 3 of the labeling includes certain "incidence of bleeding."

> puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), was the same in both groups.

See, generally, February 2002 Plavix Labeling.

B. Decedents's Medical History

Mr. Carr was a 68-year old man who had a history of coronary artery disease. In August 2000, when he was 63 years old, Mr. Carr was diagnosed with atherosclerotic cardiovascular disease. See Medical Record, Cape Girardeau Physician Assocs. (Watson Cert., Ex. C). Mr. Carr was prescribed aspirin by his cardiologist, Dr. Billy Hammond, but ceased taking aspirin on his own accord around July 2003. Id. In May 2005, Mr. Carr was admitted to the hospital emergency room following a myocardial infarction, or heart attack. See May Medical Record, St. Francis Medical Ctr. (Watson Cert., Ex. D). To treat the heart attack, Dr. Brent New, Mr. Carr's cardiac surgeon, performed a quadruple coronary artery bypass grafting ("CABG") and a right coronary endarterectomy. Id. Following surgery, Dr. New prescribed dual therapy of Plavix and aspirin for Mr. Carr. Dr. New testified in deposition that he very clearly understood that Plavix, either taken alone or with aspirin, carries with it a known risk of bleeding at the time he prescribed the drug for Mr. Carr. New Dept. at 32-33, 41 (Watson Cert. at Ex. A). Dr. New further testified that Plavix is appropriate for someone with Mr. Carr's medical condition, despite Plavix's risk of bleeding, and that he believed and continues to believe that Plavix was an

appropriate prescription for Mr. Carr. Id. at 77-80.

Dr. New recommended that Mr. Carr undergo additional surgery, in the form of a carotid endarterectomy ("CEA"), to remove plaque in the arteries leading to his brain. Sept. 20 Medical Record, St. Francis Medical Ctr. (Watson Cert., Ex. D). In order to minimize the risk of bleeding in surgery, Dr. New had Mr. Carr cease taking Plavix five days in advance of the scheduled surgery.[7] Sept. 14 Medical Record, St. Francis Medical Ctr. (Watson Cert., Ex. D). Thus, the last day Mr. Carr took Plavix was September 14, 2005. See Twidwell Dep. at 195-200 (Watson Cert., Ex. F) (deposition of Decedent's daughter).

On September 19, 2005, Dr. New performed the CEA on Mr. Carr. Sept. 20 Medical Record, St. Francis Medical Ctr. (Watson Cert., Ex. D). Dr. New observed no complications during the surgery, including any unusual bleeding or effect of Plavix in Mr. Carr. Id. Mr. Carr was discharged and instructed not to resume taking Plavix. Id. Dr. New testified in deposition that it was typical not to resume Plavix immediately following a surgery until it could be confirmed that the patient did not have any abnormal bleeding or swelling. See New. Dep. at 93-94 (Watson Cert., Ex. A).

On September 22, 2005, Mr. Carr suffered an intracerebral hemorrhage and was readmitted to the hospital for surgery and

[7] According to the Physician's Desk Reference, Plavix's effect on bleeding is eliminated about five days after its use is discontinued. See Defs. Statement, ¶¶ 5-6.

treatment; the treatment was unsuccessful and Mr. Carr died on October 10, 2005. Sept. 22 Medical Record, St. Francis Medical Ctr. (Watson Cert., Ex. D); Death Certificate (Watson Cert., Ex. G). Dr. Scott Gibbs, one of Mr. Carr's neurosurgeons during this time period, testified in deposition that Mr. Carr's intracerebral hemorrhage could have resulted from the CEA. See Gibbs. Dep. at 59 (Watson Cert., Ex. E). During surgery for Mr. Carr's hemorrhage, Dr. Gibbs testified that Mr. Carr had normal blood platelet levels and that there was no abnormal bleeding that suggested Mr. Carr was under the influence of Plavix. See id. at 50-52, 60-61 (Watson Cert., Ex. E).

C. Plaintiff's Amended Complaint

Due to the fatal intracerebral hemorrhage allegedly resulting from taking Plavix, Plaintiff, on behalf of Decedent, brings the instant survival and wrongful death suit against Defendants asserting product liability related causes of action for defective design, manufacturing defect, failure to warn, and negligence under Missouri Products Liability law, see Mo. Stat. § 537.760 et seq., and common law, and a violation of the Missouri Merchandising Practices Act, see id. § 407.010, et seq. See Am. Compl., Count I - Count IV, Count VI.[8]

Although these claims are characterized differently, they

[8] On December 30, 2009, this Court dismissed Plaintiff's claim for negligent misrepresentation (Count V). See Order dated December 30, 2009.

essentially turn on whether Defendants adequately warned that Plavix carried a risk of bleeding complications. In that regard, Defendants argue that the learned intermediary doctrine precludes Plaintiff's claim because the doctrine excuses drug manufacturers from warning Decedent, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks.

DISCUSSION

I. Standard of Review

Summary judgment is "proper if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." Pearson v. Component Tech. Corp., 247 F.3d 471, 482 n. 1 (3d Cir.2001) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)); accord Fed. R. Civ. P. 56(c). For an issue to be genuine, there must be "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party." Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir.2006); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether a genuine issue of material fact exists, the court must view the facts and all reasonable inferences drawn from those facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Curley v. Klem, 298 F.3d 271, 276-77 (3d Cir.2002).

For a fact to be material, it must have the ability to "affect the outcome of the suit under governing law." Kaucher, 455 F.3d at 423. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.

Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met this burden, the nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id.; Maidenbaum v. Bally's Park Place, Inc., 870 F.Supp. 1254, 1258 (D.N.J.1994). Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party. Anderson, 477 U.S. at 256-57. "A nonmoving party may not 'rest upon mere allegations, general denials or ... vague statements...'" Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs., 982 F.2d 884, 890 (3d Cir. 1992) (quoting Quiroga v. Hasbro, Inc., 934 F.2d 497, 500 (3d Cir. 1991)). Moreover, the non-moving party must present "more than a scintilla of evidence showing that there is a genuine issue for trial." Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). Indeed, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to

establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. Celotex Corp., 477 U.S. at 322.

Moreover, in deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. Credibility determinations are the province of the fact finder. Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

II. Missouri Failure-to-Warn Claim

Plaintiff's theory is relatively straightforward: Defendants failed to adequately warn Decedent and his prescribing physicians of the potential for bleeding complications from taking Plavix. More specifically, Plaintiff insists that Decendent's prescribing physicians were not warned regarding Plavix's propensity to cause strokes, heart attacks, abnormal bleeding and "other serious injuries and side effects." Am. Compl., ¶ 51. The parties agree that the legal sufficiency of Plaintiff's theory rests on the application of Missouri's learned intermediary doctrine, thus, to that doctrine I now turn.

A. Missouri's Learned Intermediary Doctrine

The Missouri Supreme Court adopted the learned intermediary doctrine in 1967, in Krug v. Sterling Drug, Inc., 416 S.W.2d 143

(Mo. 1967). As the Missouri Court of Appeals explained more recently, "Missouri courts adhere to the learned intermediary doctrine. . . . Missouri courts have held that in cases involving manufacturers of prescription drugs, the manufacturer has a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (citations omitted; internal quotation marks omitted) (quoting Krug v. Sterling Drug, Inc., supra, 416 S.W.2d 146).

In that connection:

> The learned intermediary doctrine is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products. . . . The physician acts as a "learned intermediary" between the manufacturer and the patient and any warning given to the physician is deemed a warning to the patient. . . . The learned intermediary doctrine provides that the failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated.

Id. at 419-420 (citations omitted; internal quotation marks omitted). In other words, "the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an

adequate warning from the manufacturer that should have been communicated to him." Id. at 420.[9]

B. Adequacy of Warning Label

Plaintiff's failure-to-warn claim fails because the learned intermediary doctrine excuses Defendants from liability in this case. As noted above, Plaintiff complains that Defendants did not adequately warn about the substantial risk of serious bleeding caused by taking Plavix with aspirin, that Plavix is ineffective for a non-smoker, and that the effectiveness of Plavix is outweighed by its increased bleeding risks in post-CABG patients. Indeed, Plaintiff dedicates much of her arguments to the effectiveness of Plavix.

As an initial matter, this Court finds that although Plaintiff presents various studies and articles challenging the efficacy of Plavix in certain types of patients, virtually none of those

[9] Plaintiff implores this Court to reject the learned intermediary doctrine when examining Missouri product liability laws. In so doing, Plaintiff relies on a decision rendered by the West Virginia Supreme Court in State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E. 2d 899 (W. Va. 2007), wherein the Court eliminated the learned intermediary doctrine in that state. As Plaintiff should be aware, because Missouri law controls in this case, this Court, sitting in diversity, is bound to follow state law as announced by the highest court in Missouri. See Nuveen Mun. Trust v. Withumsmith Brown, P.C., 692 F.3d 283, 315 (3d Cir. 2012). In this connection, the Court further notes that the Missouri Supreme Court has not revisited the learned intermediary since the West Virginia Supreme Court's decision. Accordingly, I rely upon recent Missouri Court of Appeals and federal court cases, applying Missouri law, as persuasive authority to inform my conclusion as to how the Missouri Supreme Court would rule.

studies are relevant to Decedent's medical situation.[10] Similarly, the studies upon which Plaintiff relies regarding Plavix's ineffectiveness for patients 75 years or older has no relevance since Mr. Carr was well under 75 years old when he stopped taking the drug. See Watson Cert., Ex. E. Another glaring example is Plaintiff's reliance on studies that have found that Plavix, when taken alone, is not more effective than taking aspirin by itself. See Pl. Exs. 5, 7. As Plaintiff concedes, however, Mr. Carr took Plavix in combination with aspirin, and therefore, any evidence comparing the efficacy of aspirin taken alone and Plavix taken alone has no bearing on Plaintiff's case. Overall, Plaintiff has failed to explain how any of the studies regarding efficacy -- except for the CURE study, discussed below -- are relevant to the adequacy of the warnings with respect to Plaintiff's health condition, i.e., ACS.[11] As I explained in Solomon, Slip Op. at 19-

[10] These studies include, inter alia, MATCH, CASCADE, PRODIGY, and CREDO.

[11] Plaintiff's only argument in this regard with some relevance is that Dr. Moye, Plaintiff's expert, opined that Plavix is ineffective in non-smoker patients. However, I explained in Solomon that Dr. Moye's expert report does not conclusively demonstrate that Plavix is ineffective on non-smokers. Solomon, Slip Op. at 21-22. Rather, Dr. Moye's report states that the effect of Plavix "in nonsmokers depends on the circumstances. In those indications where Plavix has a demonstrable effect, the effect in nonsmokers is also non-negative. However, in patients in whom Plavix is relatively non-effective, representing most of the patient population, Plavix remains ineffective in smokers." Dr. Moye's Report, p. 46. Hence I question whether a non-smoker warning should be required in this case.

22, because the studies are not relevant to Decedent's condition, then the failure to inform the physicians of such findings cannot establish causation.

The sole study relied on by Plaintiff and her expert, Dr. Moye, relevant to Decedent's condition is the CURE study. Plaintiff, relying on Dr. Moye's report, argues that CURE "actually failed to show any benefit of Plavix and Aspirin in patients post-CABG," such as Mr. Carr, and that "had Dr. New been informed of the lack of efficacy of Plavix for Mr. Carr's medical condition, then he would not have prescribed Plavix to Mr. Carr and exposed him to an unnecessary risk of bleeding and death." Def. Memo at 21-22.

To begin, Dr. Moye's opinion regarding the CURE study does not support Plaintiff's argument. Dr. Moye simply reiterates, without meaningful analysis or explanation, the CURE study conclusion that "CABG patients in the general population exposed to CABG and with characteristics like those of CURE patients will experience clinically negligible decreases in events associated with Plavix but will also suffer a clinically detrimental increase in bleeding." Dr. Moye's Report, p. 43. Dr. Moye did not testify that Mr. Carr fell within the scope of this conclusion, or that the CURE study demonstrates that Plavix would have been ineffective for Mr. Carr. Furthermore, Dr. Moye did not testify how the CURE study conclusion should have resulted in a different warning label for Plavix, for example, altering the risk of bleeding warning or any

other risk not currently listed on the label. In sum, Plaintiff fails to connect Dr. Moye's opinion regarding the CURE study to the Plavix label in any way.

Moreover, Plaintiff's efficacy arguments are not relevant in the context of a failure-to-warn analysis. Plaintiff's claim is essentially premised on the fact that Mr. Carr suffered substantial bleeding as a result of taking both Plavix and aspirin at the same time - not that Plavix did not work. As the Court has previously noted, in Missouri, a drug manufacturer is required to provide an adequate warning of its product if it knows of any potential harm that may result from the use of its product. In other words, a proper warning should adequately alert any danger or harm that may result from ingesting the drug. See Doe v. Alpha Therapeutic Corp., supra, 3 S.W.3d at 419(citing Krug v. Sterling Drug, Inc., supra, 416 S.W.2s at 146). Permitting Plaintiff to pursue her failure-to-warn claim on an efficacy theory would, as has been found in other jurisdictions with similar laws, impermissibly expand liability under Texas law on the adequacy of pharmaceutical warning labels. See, e.g., In re Fosamax Prods. Liab. Litig., No. 06-1789, 2010 U.S. Dist. LEXIS 33260, at *14-15 (S.D.N.Y. Mar. 26, 2010)("To allow Plaintiff to pursue a claim for the 'failure to warn' of the efficacy of a drug would be an expansion of liability

under Florida law.");[12] Tobin v. Astra Pharmaceutical Prods., Inc., 993 F.2d 528, 536 (6th Cir. 1993), abrogated on other grounds by J. McIntyre Machinery, Ltd. v. Nicastro, 131 S.Ct. 2780 (2011)(finding that the plaintiff's argument regarding the efficacy of the drug, ritodrine, should not be made in the context of a failure-to-warn claim.); Neeham v. White Labs., Inc., 639 F.2d 394, 402 (7th Cir. 1981). Thus, the studies based on the efficacy of Plavix, as presented by Plaintiff on this motion, fail to raise a genuine issue of material fact on the question of whether Plavix's warnings were adequate.[13]

In sum, on the issue of the accuracy of Plavix's warning label, Plaintiff presents a number of studies and articles which are neither relevant nor probative in demonstrating that the warnings regarding the risks of increased bleeding in ACS patients taking Plavix and aspirin were inaccurate in any way. Despite Plaintiff's assertion to the contrary, Rule 56(c) requires an entry of summary judgment against a party who fails to make a showing of the existence of an element essential to that party's case, on which that party will bear the burden of proof at trial.

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[12] The Court considers the In re Fosamax decision particularly persuasive as Missouri courts have relied on Florida law in deciding issues under the learned intermediary doctrine. See Doe v. Alpha Therapeutic Corp., supra, 3 S.W.3d at 419-420.

[13] Furthermore, as discussed infra, if the studies are not relevant to Plaintiff's condition, then the failure to inform the physicians of such findings cannot establish causation.

Therefore, without adducing evidence to show that the Plavix warning label is somehow inadequate or inaccurate, Plaintiff fails on this motion to establish the first prong of his failure-to-warn claim.

C. Proximate Cause

Although not necessary to deciding Plaintiff's motion, I briefly address the facts and parties' arguments regarding proximate cause. In Missouri, in addition to proving inadequacy, Plaintiff has to show that the allegedly defective warning label is the producing cause of Plaintiff's injury. See Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671-72 (8th Cir. 1985); Hill v. Air Shields, Inc., 721 S.W.2d 112, 118-19 (Mo. Ct. App. 1986) ("Proof of causation is an indispensable element of a plaintiff's case in products liability cases . . . ."). Thus, to prove failure to warn, Plaintiff must also show proximate cause by "show[ing] that a warning would have altered the behavior of the individuals involved in the accident." Arnold v. Ingersoll-Rand Co., 834 S.W.2d 192, 194 (Mo. 1992). Having reviewed Mr. Carr's treating physician's testimony, the Court finds that Plaintiff fails to demonstrate this element as well.

As Mr. Carr's cardiac surgeon, Dr. New testified that Mr. Carr was placed on Plavix and aspirin in 2005 because "based on the severity of [Mr. Carr's] disease, the fact that he had an endarterectomy during the coronary artery bypass procedure, it was

a very clear case for this patient to be on Plavix plus aspirin." Dr. New's Dep., T78:12-17. In addition, Dr. New explained that Mr. Carr's CAD alone qualified him to be on dual therapy, and that Mr. Carr's endarterectomy further supported the decision to place him on dual therapy. See id., T78:2-11. Importantly, Dr. New acknowledged that dual therapy could cause serious risk of bleeding in patients. Id., T33:8-18; T79:15-20. However, the cardiac surgeon insisted that despite the risks, the standard of medical practice today, let alone in 2005, is to provide the combination of Plavix and aspirin for patients like Mr. Carr. See id., T35:5-17; T39:9-41:10.

Furthermore, Dr. New testified in deposition that he did not rely on Plavix warning labels when putting Mr. Carr on dual therapy with Plavix and aspirin. Dr. New explained that he referred to the labeling "[t]o some degree. But . . . that's not the practical limit of how the medication is or should be used . . . ." Id., T46:16-18. Indeed, Dr. New testified that the label does not control his decision of when and how to prescribe a certain medication, but rather, he follows medical literature and other available information regarding his prescription decisions. See id., T47:2-19. In that regard, Dr. New represented that he typically relies on guidelines from the medical community and his colleagues' opinions rather than the labels for the drug he prescribes to patients. See id., T44:15-47:16.

Ultimately, Dr. New reiterated that he would not have prescribed anything different to Mr. Carr knowing what he knows about Plavix today:

> Q: You believe that your prescription of Plavix [plus aspirin] was appropriate for this patient; is that right?
>
> A: Yes.
>
> Q: You still believe it's an appropriate prescription today?
>
> A: Yes.
>
> Q: Do you continue to prescribe Plavix to patients who are in a similar circumstance to Mr. Carr?
>
> A: Yes.

Id., T79:18-80:1.

In light of this testimony, and Plaintiff's failure to present any testimony or evidence rebutting Dr. New, the Court finds that Dr. New was -- and still is -- aware of the risks of Plavix when he prescribed dual therapy for Mr. Carr. Courts applying Missouri law have relied on such findings to conclude, as a matter of law, that any alleged failure to warn could not be the proximate cause of Mr. Carr's injuries. See Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671-72 (8th Cir. 1985)("Picker's failure to warn Dr. Murphy could not have been the proximate cause of Kirsch's injury if Murphy was already aware of the cancer risks associated with radiation therapy. . . . Thus, the issue narrows to whether there was evidence from which the jury could have found

that Dr. Murphy did *not* know of the cancer dangers posed by the Picker machines." (citing Strong v. E.I. DuPont de Nemours Co., 667 F.2d 682, 687 (8th Cir.1981); Restatement (Second) of Torts § 388 comment k (1965); id. § 402A comment j.)).[14] Put differently, Plaintiff's proximate cause argument fails because Plaintiff cannot "show that a warning would have altered the behavior of the individuals involved in the accident." Moore v. Ford Motor Co., 332 S.W.3d 749, 762 (Mo. 2011); see also Kirsch, supra, 753 F.2d at 672 ("When viewed in a light most favorable to plaintiff, there simply is no evidence that Dr. Murphy did not know of the danger in using radiation therapy. On the contrary, the only evidence is that he had such knowledge. Any failure to warn by Picker could not have been the proximate cause of Kirsch's injuries. For this reason, the district court did not err in directing a verdict.").

Nevertheless, Plaintiff argues that summary judgment is improper because she is entitled to a presumption that Dr. New would have heeded an adequate warning. "Missouri supplies the presumption that a warning, if provided, will be read and heeded." Johnson v. Medtronic, Inc., 365 S.W.3d 226, 232 (Mo. Ct. App. 2012); see also Lemmon v. Wyeth, LLC, 4:04CV01302 ERW, 2012 WL 2848161, at *12 (E.D. Mo. July 11, 2012)(citing Arnold v. Ingersoll-Rand Co., 834 S.W.2d 192, 194 (Mo. 1992) (en banc)).

[14] Id. at 672

Plaintiff's argument is misplaced. Contrary to Plaintiff's reasoning, Missouri's heeding presumption does not apply automatically in all failure to warn cases. As the Missouri Supreme Court has explained, "the presumption that plaintiffs will heed a warning assumes that a reasonable person will act appropriately if given adequate information. Thus, a preliminary inquiry before applying the presumption is whether adequate information is available absent a warning." Moore, supra, 332 S.W.3d at 762 (emphasis added; internal quotation marks omitted). If the evidence fails to indicate that a warning would have imparted any additional information, the presumption that a warning would be heeded is not applicable. See id. "As causation is a required element of the plaintiffs' case, the burden is on plaintiffs to show that lack of knowledge." Id.

Here, the Court has already concluded that Plaintiff has failed to demonstrate the inadequacy of the current warning, and therefore that Plaintiff has not demonstrated that the warning failed to impart the necessary information. Moreover, in reviewing Dr. New's entire deposition, his testimony makes clear that the additional warning sought by Plaintiff would have had no effect on the doctor's decision to prescribe. Dr. New was aware of the bleeding risks that Plavix posed, yet he prescribed Plavix notwithstanding these risks. Dr. New reaffirmed this decision by testifying that he continues today to prescribe Plavix plus aspirin

to patients with circumstances similar to Mr. Call. Furthermore, Plaintiff's argument regarding the application of the heeding presumption is actually premised on the efficacy of Plavix, not on the risk of bleeding. As I have already concluded, however, Plaintiff has not demonstrated that Plavix lacks a warning about its risks, and thus has not demonstrated that the warning label was inadequate. For these reasons, Plaintiff is not entitled to any heeding presumption, and Plaintiff's failure to warn claim cannot withstand summary judgment on proximate cause grounds.[15]

III. Missouri Defective Design Claim

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[15] Plaintiff argues that the application of the heeding presumption and proximate cause is a question for the jury, relying in part on Lemmon v. Wyeth, LLC, Civil Action No. 04-1302(ERW), 2012 WL 2848161, at *12 (E.D. Mo. Jul. 11, 2012), a Missouri district court decision applying Missouri law. Plaintiff's reliance on Lemmon is misplaced; the Lemmon court denied summary judgment on proximate cause grounds because it had already concluded that there was a genuine issue of the adequacy of the warning. See id. at *10-12. In the present case, by contrast, I have already concluded that Plaintiff has failed to raise a genuine issue regarding the adequacy of the warning. Moreover, Plaintiff has failed to make a prima facie case that Dr. New was unaware of the danger associated with Plavix, and thus has not shown that a genuine issue exists with regard to proximate cause. Johnson, supra, 365 S.W.3d at 236 ("Medtronic established a right to summary judgment by showing that Medtronic's alleged failure to warn or alleged inadequate warning was not the proximate cause of Jeffrey Johnson's injuries."); see also Tune v. Synergy Gas Corp., 883 S.W.2d 10, 14 (Mo. 1994) ("there is sufficient evidence from which a jury could find that the plaintiff did not already know the danger . . . [and this question gives rise to the] presumption that a warning will be heeded").

In order to prove a design defect claim under Missouri law, a plaintiff must establish that the defendant sold its product in the course of its business, the product was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use, the product was used in a manner reasonably anticipated, and the plaintiff was damaged as a direct result of this defect. See Duke v. Gulf & Western Mfg. Co., 660 S.W.2d 404, 410 n.4 (Mo. Ct. App. 1983).

In the present case, Plaintiff's design defect claim is premised on the same arguments regarding efficacy that Plaintiff advanced in her failure to warn claim. See Opp. Br. at 29 (arguing that summary judgment must be denied as to the defective design claim "because a genuine issue of fact exists as to whether Mr. Carr received any benefit from his Plavix use"). To that end, Plaintiff opposes Defendants' summary judgment motion on the basis that Defendants have failed to demonstrate the application of comment k to Section 402A of the Restatement (Second) of Torts. I need not reach the parties' arguments regarding comment k, however, because Plaintiff has submitted no evidence that Plavix is "'unreasonably dangerous' and therefore defective." See Nesselrode v. Executive Beechcraft, Inc., 707 S.W.2d 371, 375-76 (Mo. 1986). Plaintiff thus has failed to carry its burden of establishing a prima facie design defect claim. See id.

IV. Missouri Manufacturing Defect Claim

For the same reason as discussed in connection with her design defect claim, Plaintiff also fails to make a prima facie case with respect to her manufacturing defect claim. Duke, supra, 660 S.W.2d at 411 ("[T]he Missouri Supreme Court [has] found "no rational distinction" between the manufacture and the design of a product in the strict liability context and [has] reaffirmed that a product may be found to be 'unreasonably dangerous' and actionable . . . when it is 'defective and dangerous when put to a use reasonably anticipated.'"). Accordingly, Plaintiff has failed to sustain her burden on this summary judgment motion. Moreover, Plaintiff's argument that Defendants must proffer evidence that Plaintiff has no viable manufacturing defect claim is misplaced. See Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1362 (3d Cir. 1992) ("[In summary judgment t]he moving party need not produce evidence to disprove the opponent's claim . . . .").

V. Negligence Claim

Plaintiff's negligence claim is nothing more than a restatement of her defective design, defective manufacturing, and failure-to-warn claims. Plaintiff avers that Defendants negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold Plavix. See Am. Comp., ¶¶ 68-71. Because the Court has found that none of her claims have merit, this claim necessarily fails.

VI. Missouri Merchandising Practices Act Claim

Plaintiff's Missouri Merchandising Practices Act ("MMPA") claim also is based on the same arguments Plaintiff advances in connection with her Missouri Products Liability law claims, i.e., "Dr. New would not have prescribed Plavix to Mr. Carr if [Dr. New] had known about the true lack of efficacy and increased risk of bleeding . . . ." See Opp. Br. at 33-34. For the reasons discussed above, Plaintiff cannot prove that Plavix caused the Decedent's injuries, and therefore cannot make a prima facie case under the MMPA. See Owen v. General Motors Corp., 533 F.3d 913, 922 (8th Cir. 2008) ("[T]o successfully present an MMPA claim, the [plaintiff] must demonstrate that [she] purchased personal merchandise and that [she] suffered an ascertainable loss as a result of [defendant's] use of one of the methods or practices declared unlawful by [Mo. Rev. Stat. §] 407.020." (Emphasis added.)).

VII. Discovery Request Pursuant to Rule 56(d)

As a final note, Plaintiff seeks additional discovery pursuant to Fed. R. Civ. P. 56(d). Based on the Court's ruling herein, there is no basis to provide Plaintiff additional opportunities to seek discovery. Moreover, much of what Plaintiff proposes to discover relates to Plavix's effectiveness, which, for the reasons explained in my opinion in Solomon, supra, is neither relevant nor probative of Plaintiff's claims. Also, Plaintiff has had the opportunity to take the depositions of Decedent's treating

physicians, Dr. New and Dr. Gibbs. As the Court has already found that the physicians' testimonies do not support Plaintiff's claim in light of the learned intermediary doctrine, additional discovery would not lead Plaintiff to any new evidence that would change the results here. Accordingly, Plaintiff's position that the motion is premature and further discovery should be taken is rejected.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in its entirety. As a result, Plaintiff's Amended Complaint is dismissed.

An appropriate Order shall issue.

Dated: January 28, 2013

/s/ Freda L. Wolfson

The Honorable Freda L. Wolfson
United States District Judge